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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,293	08/20/2003	John R. Peery	ARC2437USCON6	7202

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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/645,293	PEERY ET AL.	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/21/08*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-73, 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-73, 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/21/07 has been entered.

Status of Claims

Claims 51-73, and 75 are pending in the application.

Status of Office Action: Non-Final

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 54 and 70 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim recites “the reservoir comprises a metal capsule”. There is no support in the specification for a metal capsule in the reservoir. Applicant is required to show citation for the support of the recitation. This is a new matter rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 51-73, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Laby et al. US 4623330 in view of Portner et al. US 4,360,019 (Hereinafter "Portner"), Magruder et al. US 5238687 (hereinafter "Magruder") and further in view of Mia US 5519002 (hereinafter "Mia").

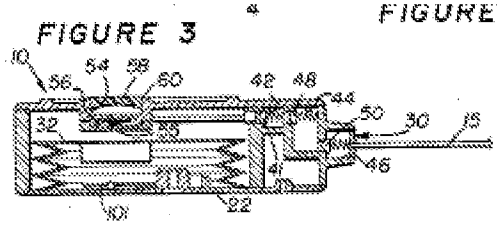
Laby teaches an implantable device (example 4), for delivering a pharmaceutical and veterinary applications (col. 1, lines 5-10). A hollow tubular body adapted to contain a solid, paste or liquid material, one end of said body being at least partly open to allow egress of the material, the other end of said body being closed, a gas tight plunger adapted for slidable movement within the body (col. 1, lines 57-63). The hollow body portion comprises a cylindrical tube open at one end, the other end having a base supporting a helical spring to which a plunger is attached which plunger is capable of being urged by the spring toward the opening (col. 1, lines 43-47). The helical spring is made from spring steel wire having a circular cross-section of 0.5 mm in diameter (0.0197 inch), which is within the range set forth in claim 52. Laby also discloses a radially expanding disc to ensuring good tight contact between the piston and the walls of the body (col. 2, lines 62-67).

Laby describes the dimensions of his implantable system as having a body length of 14 cm and a diameter of 2.8 cm for use in cattle, and a length of 9 cm and a diameter of 1.6 cm for use in sheep. The helical spring is made from spring steel wire having a circular cross-section of 0.5 mm in diameter. The spring comprises 20 to 30 coils and is capable when fully compressed of exerting a pressure of approximately 600 g (cattle) and 300 g (sheep). It would have been obvious to an ordinary skilled man in the art to adjust these dimensions according to the human body.

Laby fails to disclose the helical path flow that regulates the back diffusion through the outlet.

Portner teaches an infusion system for delivering precisely regulated and variable dosages of drugs. The device includes a reservoir for containing the drug, a catheter for delivering drug to the body, and actuating means responsive to a signal applied externally of the body for initiating delivery of a precisely regulated dosage (abstract). The system is implantable (claim 1), and the drug is prevented from flowing back into the reservoir by the valve which is a spring-loaded in the normally closed position (col. 4, lines 44+), the reference also teaches the use of membranes such as self-120

ing membrane for allowing injection of a drug supply into said reservoir means and further comprising a redundant check valve means in series with said membrane for preventing escape of the drug supply from said reservoir through said inlet means (claim 12).



It would have been obvious to one of ordinary skills in the art to us a spring as a valve at the outlet of drug implantable system to regulate the drug release and prevent the back diffusion of the external fluids because portner teaches that the drug can be prevented from flowing back.

Laby and portner fail to disclose the semipermeable membrane system recited in the instant claims.

Magruder discloses a delivery implantable device that includes a sleeve to protect the delivery device from transient mechanical forces. The invention provides a fluid-imbibing delivery device comprising a housing enclosing an internal compartment having a first wall section that substantially restricts the passage of fluid into the delivery device, i.e. is substantially fluid-impermeable (abstract). The implantable device contains at least one expandable driving member (abstract). The composition of the circumferential sleeve may be of a semipermeable material made of polyamide or polyurethane (col. 9, lines 22, and 23), or in a preferred embodiment, they are selected from the group consisting of a cellulose ester, a cellulose ether and a cellulose ester-ether, which are cellulosic polymers (col. 9, lines 62-64). The invention comprises a lubricated elastomeric piston inserted on top of the osmotic device to be flush with the top of the semipermeable walled member (col. 15, lines 5-8).

It would have been obvious to one of ordinary skill in the art to upgrade the membranes disclosed by Portner and use a semipermeable membranes as it restricts the passage of fluid into the delivery device, i.e. is substantially fluid-impermeable.

None of the references discloses LHRH agonists.

Mia teaches a method for preventing conception in mammals, the drug used is LHRH agonists (abstract and claim 1) and the administration method can be an implant (claim 8). The

effect of the drug conjugate starts from about 6 weeks after administration until the LHRH antibodies formed in response to the conjugate are metabolized, generally about 0.5-2 years (abstract), in a preferred embodiment a composition comprising free LHRH or an analog thereof and an immunogenic conjugate between a protein mixtures thereof is administered to mammals to prevent conception over the period from initial injection to about 2-3 years (col. 3, lines 33-44).

Regarding the new amendments to the claims, it is noted that in Portner the reservoir (12) and the regulator (13) are in mating relation and the flow path (34) is between the mating surfaces (see Fig. 2). Further, the diffusion regulating valve is made of an elastomer (thermoplastic rubbers) and the housing (22) -which is part of housing (12)- is made of stainless steel or titanium (col. 4, lines 11+). Finally, Portner discloses that the most common type of drug delivery systems employed for complete implantation and known in the art includes a permeable membrane for controlled diffusion of a drug into the body from a suitable reservoir, this is disclosed by Magruder wherein the reference teaches that the sleeve may be of a semipermeable material made of polyamide or polyurethane (col. 9, lines 22, and 23). Thus, none of these amendments would differentiate the instant claims over the prior art.

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the implantable device of Laby and combine it with the spring regulated drug delivery system at the outlet and provide it with the sleeve made of cellulosic material or polyurethane to administer LHRH agonist because Mia states that the invention is effective in mammals soon after administration of the composition and stay effective for extended period. The expected result would be an implantable device that delivers LHRH for an extended period of time.

Response to Arguments

Applicant's arguments filed 8/14/07 have been fully considered but they are not persuasive. Applicant argues that:

Claims 51, 52, 53, 54, 57, 58, 65-72, and 75:

- Laby et al., Portner et al., Magruder et al., and Mia, in combination, do not disclose or teach an implantable or fluid-imbibing device in which a reservoir and a back diffusion regulating outlet have surfaces in a mating relationship, wherein a helical flow path is formed between the mating surfaces, as recited in claims 51, 52, 53, 54, 57, 58, 65-72, and 75.

To respond: As shown above, Laby teaches an implantable device for delivering an active agents. A hollow tubular delivering for example a liquid material, one end of said body being at least partly open to allow egress of the material, the other end having a base supporting a helical spring to which a plunger is attached which plunger is capable of being urged by the spring toward the opening. Portner teaches that the reservoir (12) and the regulator (13) are in mating relation and the flow path (34) is between the mating surfaces (see Fig. 2).

- The spring, as used in Portner et al., does not define a helical flow path between the valve body and the reservoir. Moreover, the Portner et al. system requires a pumping device to pressurize the fluid in the reservoir in order to overcome the force of the spring. In the instant application, the helical flow path remains open and naturally regulates back diffusion so that a separate pumping device is not needed to deliver fluid from the reservoir.

To respond: As shown above Portner teaches that the reservoir (12) and the regulator (13) are in mating relation and the flow path (34) is between the mating surfaces (see Fig. 2). In addition, instant claims do not exclude a pumping device to pressurize the fluid in the reservoir.

Claims 55 56 59 60 61-64 and 73:

- Laby et al., Portner et al., Magruder et al., and Mia, in combination, do not disclose or teach an implantable or fluid-imbibing device having a semipermeable plug that is received in sealing relationship with an interior surface of a reservoir and wherein an exterior surface of the semipermeable plug has circumferential ridges.

To respond: Laby teaches an implantable device for delivering active agents. A hollow tubular delivering for example a liquid material, one end of said body being at least partly open to allow egress of the material, the other end having a base supporting a helical spring to which a plunger is attached which plunger is capable of being urged by the spring toward the opening. Portner teaches that the reservoir (12) and the regulator (13) are in mating relation and the flow path (34) is between the mating surfaces (see Fig. 2). Magruder teaches the delivery implantable device that provides a fluid-imbibing delivery device comprising a housing enclosing an internal compartment having a first wall section that substantially restricts the passage of fluid into the delivery device and a second wall that that contains at least one expandable driving member; and exit means; with a protective sleeve means. The composition of the circumferential sleeve may be of a semipermeable material made of polyamide or polyurethane. Mia teaches the use of LHRH in an implantable device. Accordingly, the instant claims renders obvious over the combination of Laby, Portner, Magruder, and Mia.

- The Examiner has suggested that because Magruder makes the protective sleeve from a semipermeable material, it would be obvious to make the releasable septum from a semipermeable material. However, these elements, releasable septum and protective sleeve, are materially different in function and it is not obvious at all that what applies to the releasable septum also applies to the protective sleeve. Moreover, making the releasable septum from a semipermeable material would not disclose or teach a semipermeable plug having an exterior

surface with circumferential ridges, as recited in claims 55, 56, 59, 60, 61-64, and 73. Perhaps the Examiner is considering replacing the releasable septum with the protective sleeve. However, if the releasable septum is replaced with the protective sleeve, the check valve (56) would be open always, without the protection of the releasable septum. In a fluid environment, fluid would constantly enter the reservoir, contaminating the drug in the reservoir. Further, replacing the releasable septum with the protective sleeve would not disclose or teach a semipermeable plug having an exterior surface with circumferential ridges, as recited in claims 55, 56, 59, 60, 61-64, and 73.

To respond: Magruder teaches the delivery implantable device that provides a fluid-imbibing delivery device comprising a housing enclosing an internal compartment having a first wall section that substantially restricts the passage of fluid into the delivery device and a second wall that that contains at least one expandable driving member (swellable); and exit means; with a protective sleeve means. The composition of the circumferential sleeve may be of a semipermeable material made of polyamide or polyurethane. Mia teaches the use of LHRH in an implantable device. Accordingly, the sleeve is a part of the releasing system, and it renders the releasing system of the instant claims obvious since it is within the ability of a person of ordinary skill in the art to use the materials disclosed by Magruder in the delivery system as needed by the device.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618